

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 1/21/2025-1/28/2025* FEI NUMBER 3011213917
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Mina NMI Kalantari, Chief Scientific Officer (CSO)/Laboratory Manager

FIRM NAME MD Tox Laboratory	STREET ADDRESS 1565 McGaw Avenue, Suite A/B
CITY, STATE, ZIP CODE, COUNTRY Irvine, CA 92614-5634	TYPE ESTABLISHMENT INSPECTED Testing Laboratory

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

A quality program which addresses all of the core CGTP requirements, appropriate for the HCT/Ps manufactured and the manufacturing steps performed, has not been defined and followed.

Specifically, your firm's quality program has not been defined or followed for the following:

1. The following temperature/humidity excursions occurred in the refrigerators or FDA Testing areas below:

- a. Fridge (b) (4) (Sample Storage)
- b. Fridge (b) (4) (Sample Storage)
- c. Fridge (b) (4) 1 (Reagents Storage)
- d. (b) (4) Room
- e. (b) (4) Room

Nonconformances were not documented or investigated addressing the excursions above.

According to procedure entitled, "Temperature Log Procedure, Version 1.0, Effective Date: 04/01/2024" Section 6.4 states: "Normal refrigerator temperature range for refrigerators is considered between (b) (4) °C)." Sections 6.6 – 6.6.3 state: "6.6. **IMPORTANT: If the temperature is out of range, proceed to the following steps:** 6.6.1. Close the fridge/freezer door and tag the instrument as "Do Not Open". 6.6.2. Leave the instrument closed for at least (b) (4). 6.6.3. After (b) (4), recheck the temperature, if the temperature is still abnormal,

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record the temperature and notify the Supervisor immediately.”

According to procedure entitled, “Temperature Log Procedure, Version 1.0, Effective Date: 04/01/2024” Section 6.8 – 6.9 state: “6.8. Normal room temperature range is considered between (b) (4)°C 6.9. Normal humidity range for freezers is considered between (b) (4)%.”

According to procedure entitled, “Temperature Log Procedure, Version 1.0, Effective Date: 04/01/2024” Sections 6.11 – 6.11.3 state: “6.11 **IMPORTANT: If the temperature is out of range, proceed to the following steps:** 6.11.1 Adjust the room temperature to make it colder/warmer as needed and recheck in (b) (4) . 6.11.2. If the temperature is still abnormal, write down the temperature and notify the Supervisor immediately. 6.11.3. The lab designee will follow-up to ensure corrective action is taken.”

2. Your preventative maintenance for the following equipment was not provided:

- a. (b) (4)
 - i. (b) (4) Preventative Maintenance for:
 1. (b) (4) 2024
 2. (b) (4) 2024
 3. (b) (4) 2024
 4. (b) (4) 2024
 5. (b) (4) 2024
 6. (b) (4) 2024
 7. (b) (4) 2024
 8. (b) (4) 2024
 9. (b) (4) 2024
 10. (b) (4) 2024
 - ii. (b) (4) System Test Report for:
 1. (b) (4) 2024

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2. (b) (4) 2024
3. (b) (4) 2024
4. (b) (4) 2024
5. (b) (4) 2024
- iii. (b) (4) Quality Management Summary
 1. (b) (4) 2023
 2. (b) (4) 2024
- b. (b) (4)
 - i. Maintenance Checklist
 1. (b) (4) 2024 – (b) (4) 2024, (b) (4) 2024
 - ii. (b) (4) Quality Management Summary
 1. (b) (4) 2023
 2. (b) (4) 2024
- c. (b) (4)
 - i. Maintenance Checklist
 1. (b) (4) 2024
 - ii. (b) (4) Quality Management Summary
 1. (b) (4) 2024
- d. (b) (4)
 - i. (b) (4) Maintenance for the week of:
 1. (b) (4) 2023
 - ii. (b) (4) Preventative Maintenance
 1. (b) (4) 2023 – (b) (4) 2023
 - iii. (b) (4) Quality Management Summary
 1. (b) (4) 2023
 2. (b) (4) 2024
- e. (b) (4)
 - i. (b) (4) Preventative Maintenance
 1. (b) (4) 2023 – (b) (4) 2024

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- f. (b) (4) QC (b) (4) Log
- i. (b) (4) QC
1. (b) (4) 2024
 2. (b) (4) 2024
 3. (b) (4) 2024
 4. (b) (4) 2024
- g. (b) (4) Logs
- i. (b) (4)
1. (b) (4) 2024 ((b) (4) Room)
 2. (b) (4) 2024 ((b) (4) Room)

This equipment is used during manual (b) (4) testing or machine automated (b) (4).

THIS IS A REPEAT OBSERVATION.

OBSERVATION 2

Procedures appropriate to meet core CGTP requirements for all steps that you perform in the manufacture of HCT/PS were not defined and followed.

Specifically,

Your firm has not defined in your procedure entitled, "Procedure for repeating and reporting (b) (4) samples ((b) (4)), Version 1.0, Effective Date: 07/31/2023" the following manufacturing steps regarding review, sign-off, and release of final test results to a client are captured. For example, data entry and/or transfer into your (b) (4) system was not described. The (b) (4) review and documentation of the performed reviewed were also not described.

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Additionally, your firm has not defined in your procedures regarding storage of samples, storage times, and traceability. During the inspection, I observed several employees were going to different areas of the laboratory to find the samples they were needed to run the appropriate tests; the samples were laying on several different tabletops in racks for hours with no traceability and at room temperature.

Since August 2023, your firm has performed (b) (4) tests on samples.

THIS IS A REPEAT OBSERVATION.

OBSERVATION 3

Records were not detailed as necessary to provide a complete history of work performed.

Specifically, during the inspection when I reviewed quality control and preventative maintenance records from August 2023 – December 2024 for the equipment and areas below, the following were missing documentation of review by signature and date:

- a. (b) (4)
- b. (b) (4)
- c. (b) (4)
- d. (b) (4)
- e. (b) (4)
- f. (b) (4) QC (b) (4) Log
- g. Refrigerator (b) (4)
- h. Refrigerator (b) (4)
- i. Refrigerator (b) (4)
- j. (b) (4) Room
- k. (b) (4) Room

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Investigator
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OBSERVATION 4

Records were not retained for the appropriate length of time, 10 years after their creation.

Specifically, your firm's (b) (4) is programmed to store test results for (b) (4). Your firm does not have the original testing data prior to (b) (4).

THIS IS A REPEAT OBSERVATION.

OBSERVATION 5

A records management system relating to core CGTP requirements was not maintained and documented.

Specifically, during the inspection I reviewed quality control records regarding refrigerator temperature, room temperature, and humidity, however your firm was unable to provide quality control records for the following:

- a. Refrigerator (b) (4) (Sample Storage)
- b. Refrigerator (b) (4) (Sample Storage)
- c. Refrigerator (b) (4) (Reagent Storage)
- d. (b) (4) Room
- e. (b) (4) Room

***DATES OF INSPECTION**

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1/21/2025(Tue), 1/22/2025(Wed), 1/23/2025(Thu), 1/24/2025(Fri), 1/27/2025(Mon), 1/28/2025(Tue)

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Celeta S Coves, Investigator

Celeta S Coves
Investigator
Signed By: Celeta S. Coves -S
Date Signed: 01-28-2025
12:45:01

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."